Information for Healthcare Professionals
Desmopressin Acetate (marketed as DDAVP Nasal Spray, DDAVP Rhinal Tube, DDAVP, DDVP, Minirin, and Stimate Nasal Spray)

FDA ALERT [12/4/2007]: FDA has requested the manufacturers update the prescribing information for desmopressin to include important new information about severe hyponatremia and seizures.

Certain patients taking desmopressin are at risk for developing severe hyponatremia that can result in seizures and death. Children treated with desmopressin *intranasal* formulations for primary nocturnal enuresis (PNE) are particularly susceptible to severe hyponatremia and seizures. As such, desmopressin *intranasal* formulations are no longer indicated for the treatment of primary nocturnal enuresis and should not be used in hyponatremic patients or patients with a history of hyponatremia. PNE treatment with desmopressin *tablets* should be interrupted during acute illnesses that may lead to fluid and/or electrolyte imbalance. *All* desmopressin formulations should be used cautiously in patients at risk for water intoxication with hyponatremia.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

To report any unexpected adverse or serious events associated with the use of this drug, please contact the FDA MedWatch program and complete a form on line at http://www.fda.gov/medwatch/report/hcp.htm or report by fax to 1-800-FDA-0178, by mail using the postage-paid address form provided on line, or by telephone to 1-800-FDA-1088.

FDA has requested that the prescribing information for all desmopressin products be updated with new information about the risk for hyponatremia and how to safely use desmopressin.

- The **intranasal formulations** are no longer indicated for treating primary nocturnal enuresis. The new information about the risk for hyponatremia can be found in DDAVP's INDICATION AND USAGE, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, DOSAGE and ADMNISTRATION, and HOW SUPPLIED sections of the prescribing information and the PATIENT INSTRUCTION GUIDE. Label The other desmopressin product's labeling will be similarly updated. All other approved indications of the individual intranasal formulations still remain.
- For DDAVP's **desmopressin tablets, rhinal tube**, and **injections** Label the new information about the risk for hyponatremia can be found in the CONTRAINDICATIONS, WARNINGS, and DOSAGE and ADMNISTRATION sections of the prescribing

information.

Recommendations and Considerations

- **Desmopressin *intranasal* formulations are no longer indicated for the treatment of primary nocturnal enuresis due to serious hyponatremia that may result in seizures and death.** Doctors should consider other options for managing this condition.

- **Desmopressin *tablets*:**

    - **Treatment for primary nocturnal enuresis should be interrupted during episodes of fluid and/or electrolyte imbalance,** such as fever, recurrent vomiting or diarrhea, vigorous exercise, or other conditions associated with increased water consumption.

    - **Fluid intake should be restricted from 1 hour before to 8 hours after administration of desmopressin tablets.**

- ***All* desmopressin formulations should be used cautiously in patients with habitual or psychogenic polydipsia or in patients who are taking drugs that may cause them to drink more fluids, such as tricyclic antidepressants and selective serotonin re-uptake inhibitors (SSRIs).** Patients taking desmopressin and consuming excessive fluids are at higher risk of developing hyponatremia.

Information for the patient: *Physicians who prescribe desmopressin should discuss with their patients:*

Desmopressin works by limiting the amount of water that is eliminated in the urine. A healthy body needs to maintain a balance of water and salt ("sodium"). If sodium levels fall too much ("hyponatremia"), a person may have seizures and, in extreme cases, may die. That is why it is important to monitor your or your child's water intake. A person's chance of water and sodium imbalance is increased

- if they are taking certain medicines such as antidepressants, painkillers, and medicines to treat seizures that may make the mouth dry
- during hot weather or following strenuous exercise that may make them thirsty
- if they are sick and have severe vomiting and diarrhea, fever, the flu, or severe cold

Therefore, if you or child are prescribed desmopressin, it is important that you

- tell your doctor about other medicines you or your child are taking
- tell your doctor if you or your child has a history of hyponatremia
- supervise the use of desmopressin in your child if it is administered in the nose for the remaining indications
- restrict fluid intake from 1 hour before to 8 hours after taking desmopressin tablets
- promptly contact your doctor if your or your child's water intake changes
- promptly contact your doctor if symptoms of hyponatremia occur, such as nausea, vomiting, fatigue, muscle cramps or weakness

Background Information and Data

Desmopressin is a synthetic analogue of vasopressin, an antidiuretic hormone that prevents excessive water loss in the urine. Desmopressin in combination with excessive fluid consumption can result in hyponatremia, an imbalance between intracellular and extracellular sodium. This imbalance can lead to seizures, brain swelling, and death.

FDA has reviewed 61 postmarketing cases of hyponatremic-related seizures associated with the use of desmopressin. Fifty-five cases reported sodium levels ranging from 104 to 130 mEq/L during the seizure event. In two cases, the patients died. Both patients experienced hyponatremia and seizures but the direct contribution of desmopressin to the deaths is unclear. Thirty-six cases were associated with intranasal formulations, of which 25 cases occurred in pediatric patients (<17 years old). The most commonly reported indication of use in these 25 pediatric cases was nocturnal enuresis. Thirty-nine of the 61 cases were associated with at least one concomitant drug or disease that is also associated with hyponatremia and/or seizures.

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Date created: December 4, 2007